

REMARKS

Claims 1-5 are canceled. Claims 9-21 are withdrawn. Applicant has amended claim 6 to clarify the operation of the injection device. No new matter has been added. Support for the amendment is found throughout the specification, e.g., at page 7, lines 12-15; page 8, lines 1-4 and lines 19-22; and Figs. 1-4. Claims 6-8 and 22-25 are pending.

Obviousness-Type Double Patenting

Claims 6-8 and 22-24 remain rejected as allegedly unpatentable over claim 1 of U.S. Patent No. 5,695,463 (the '463 patent) in view of U.S. Patent No. 5,242,416 (Hutson). Applicant respectfully traverses the rejection as to the currently amended claims.

Applicant disagrees with the Office Action's assertion (at page 2) that claim 1 in '463 patent "discloses the invention substantially as claimed." The device disclosed in claim 1 of '463 patent (the '463 device) is significantly different from the devices of the present invention. Applicant has amended Claim 6 to emphasize the differences. For example, the present amendment clarifies that prior to pushing the plunger of a claimed device, a drug composition is isolated from the needle by a septum plunger. The composition is exposed to the needle only upon piercing the septum plunger during injection.

Unlike the currently claimed devices, the '463 device does not include a septum plunger configured to isolate an injectable composition from the needle prior to pressing the plunger during injection. In fact, the '463 device cannot use such a septum plunger, because it requires that the injectable composition be located inside the needle prior to injection.

To elaborate this point, Claim 1 of the '463 patent recites "a rod within said needle, said rod extending through said main body ...and affixed to said plunger" of the device..."wherein said plunger and rod are operative to push the medicament through said needle into said mammal, as the needle is being withdrawn from said mammal" ('463 patent at column 4, lines 6-

8 and 17-20). Applicant also refers the Examiner to Figs. 1-4 of '463 patent.¹ The Figures and specification clearly indicate that in the '463 device, "a rod 16 is guided into needle 12 and abuts medicament 20 which is positioned in the needle 12" (column 2, lines 50-51). In the '463 device, pressing the plunger causes the rod, located within the needle, to push a medicament, which is also located within the needle, through said needle and into a mammal. Thus, the prior art device is clearly different from the presently claimed device.

Applicant also submits that a person of skill in the art would not have been motivated to alter the '463 device to isolate the composition from the needle, because such a modification would render the prior art device unsuitable for its intended purpose. A composition isolated outside of the needle in the '463 device could not be pushed from the housing into and through the needle, because the rod recited in the '463 patent (which is "inside said needle") would prevent the movement of the composition from the housing into the needle. Thus, applicant submits that adapting the '463 device to the currently amended claims would require removing the rod recited by claim 1 in the '463 patent. However, the prior art provides no suggestion or motivation to remove this rod.

Furthermore, adapting the '463 device to the currently amended claims would *change the principle of operation* explicitly recited by claim 1 of the '463 patent. The currently claimed device uses an increase of pressure within the housing, caused by depressing the plunger, to pierce a septum plunger and subsequently push a composition from the housing into the needle. On the other hand, claim 1 of '463 patent requires that the rod be "operative to push medicament through the needle." In this regard, applicant reminds the Office that if a "proposed modification would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the current claims *prima facie* obvious." MPEP 2143.01 *citing In re Ratti*, 270 F.2d 810 (CCPA 1959).

The additional reference cited in the Office Action is U.S. Patent No. 5,242,416 (Hutson), which is cited for disclosing a protective sleeve covering the needle. However, this disclosure does not make up for the differences between the '463 patent and the currently amended claims.

¹ As stated in MPEP 804, 1, "those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." Citing *In re Vogel*, 422 F.2d 438, 441-42, (CCPA 1970).

Applicant submits that a person of skill in the art would not have been motivated to modify the '463 device to (i) eliminate the rod, (ii) abandon the operative principle of using a rod to push a composition through a needle, and (iii) add a septum plunger configured to isolate an (injectable) composition from the needle prior to injection, (iv) such that, during injection, the needle pierces the septum plunger and the composition is pushed into and through the needle.

In view of the current amendments, applicant submits that the cited references do not establish a *prima facie* case of obviousness. Therefore, applicant respectfully requests that the rejection be reconsidered and withdrawn as to claims 6-8 and 22-24.

Claim 25 stands rejected as allegedly unpatentable over claim 1 of the '463 patent in view of Hutson and U.S. Patent No. 5,399,170 (Whitley). Applicant respectfully traverses the rejection.

As explained in detail above, the '463 patent, either alone or in combination with Hutson, does not disclose the invention of the currently amended claims. Whitley is cited as describing a releasable lock to prevent movement of the plunger prior to use. However, Whitley does not make up for the differences between the '463 patent and Huston and the presently claimed invention. Thus, even when combined, these three references do not suggest or provide a motivation to (i) remove the rod limitation, (ii) add a septum plunger to the housing to isolate an injectable composition in a portion external to the needle, and (iii) change the principle of operation in the '463 patent to no longer use a rod to push composition located in the needle (iv) in such a way to as to arrive at the currently amended claims. Therefore, the office has failed to establish a *prima facie* case of obviousness against amended claim 25.

Additionally, Whitley does not appear to disclose a releasable lock that prevents movement of the plunger into the housing, as recited by claim 25. Whitley discloses a pair of "safety locks" 15 and a pair of stops 23 that, when engaged, prevent further movement of the plunger 9 into the inner sheath 4 of the device. However, even when engaged, these locks 15 do not prevent the plunger 9 from moving into the outer sheath 3, until inner sheath shoulders 16 engage outer sheath shoulders 17. Figures 11 and 12 in Whitney show that even with "safety locks" 215 and stops 223 engaged, the plunger 209 continues to move into the outer sheath 203

until the inner sheath shoulder (not numbered) and outer sheath shoulder (not numbered) are engaged. Thus, the "safety locks" disclosed in Whitley are not configured to prevent a plunger from moving into the housing, and do not meet the recited limitations of claim 25. The Office Action does not account for this difference between the current claims and the Whitley disclosure, nor does the rejection provide a suggestion or motivation to modify the Whitley mechanism (that prevents plunger movement into an inner sheath, but appears to allow plunger movement into an outer sheath) to arrive at the currently claimed releasable lock that prevents plunger movement into a syringe housing.

For the reasons presented above, applicant respectfully requests that this rejection be reconsidered and withdrawn as to claim 25.

35 U.S.C. §103(a)

Claims 6-8 and 22-24 remain rejected as allegedly unpatentable over U.S. Patent No. 5,634,906 (Haber) in view of Hutson. Applicant respectfully traverses this rejection because (i) the cited references fail to teach or suggest all of the currently claimed elements and (ii) the rejection has not identified a motivation or suggestion to modify prior art so as to arrive at the devices as currently claimed.

Neither Haber nor Hutson teaches a septum plunger (i) contained in the housing and (ii) configured to isolate an injectable composition from the needle prior to injection, such that (iii) the needle is exposed to the composition only after piercing the septum plunger during injection. Thus, these two references, either alone or in combination, do not teach all of the elements recited by the currently amended claims; and they are insufficient to establish a *prima facie* case of obviousness against the claims as amended.

Applicant also respectfully submits that the Office Action has misconstrued Haber. Contrary to statements at pages 4 and 6 of the Office Action, Haber does not appear to disclose or suggest any embodiments in which a travel limit sleeve (referred to by the Office as a "hollow sleeve") 24 is "slidably connected to the distal end of the housing" (defined by the Office to include 6, 26, and 42) during injection. In fact, Haber specifically states that the travel limit sleeve 24 is "frictionally retained within the distal end of the outer sleeve guard 8 to limit the

travel of the cartridge housing and the hypodermic needle during the administration of the injection” (Column 2, lines 61-65, reference number added; see also column 4, lines 48-49). In this regard, applicant notes that elements **8** and **6** in Haber are the distal and proximal end, respectively, of the outer sleeve guard. Thus, the travel limit sleeve is “frictionally retained” to the distal end of the outer sleeve guard that the Office includes as part of the housing. For this reason, applicant respectfully submits that the travel limit sleeve **24** is not “slidably connected to the distal end of the housing.”²

Furthermore, applicant submits that Figs. 3 and 4 do not appear to show that travel limit sleeve **24** is retractable into any of elements **6**, **26**, or **42**. Generally, this can be understood as a consequence of the intended function of travel limit sleeve **24** as a “stopper.” When a user of the Haber device presses the plunger (as shown in Figure 4), the force causes inner sleeve **12**, the cartridge housing **26**, and inner spring posts **16** to travel distally towards the travel limit sleeve **24**. When one or more of these elements contact travel limit sleeve **24**, travel limit sleeve **24** acts as a stopper that prevents further distal movement of inner sleeve **12** and cartridge **26** thereby permitting “hypodermic needle (36) to extend only to its full length necessary for administering the injection” (Haber, column 4, lines 50-52). In acting as a “stopper” that prevents the further distal movement of elements (36), **26**, and **12**, the travel limit sleeve **24** remains outside of, and does not retract into, any portion of the device that the Office has identified as part of the housing.

For completeness, applicant discusses why Haber does not disclose the travel limit sleeve as retractable into each specific element that pages 6 and 8 of Office Action define as parts of the housing in Haber. As to element **6**, Haber characterizes the travel limit sleeve **24** as “frictionally retained,” i.e., fixed to distal end of *outer sleeve guard* **8**. Thus, it is not retractable into the proximal end of *outer sleeve guard* **6** (applicant again notes that **8** and **6** in Haber are the distal and proximal end, respectively, of the same *outer sleeve guard*). Nothing in Figs. 3 and 4 contradicts this characterization. As to element **26**, the travel limit sleeve **24** appears to be incapable of retracting into cartridge housing **26** in Figs. 3 and 4, because (i) travel limit sleeve **24** is depicted as having a wider diameter than cartridge housing **26** and (ii) spring posts **16**

² In Haber, The travel limit sleeve **24**, fixed with respect to the distal outer sleeve guard **8**.

appear to block progression of the travel limit sleeve **24** into the cartridge housing **26**. This view is supported by the specification at column 6, lines 21-26, where Haber explains that, during injection, the cartridge housing **26** and needle (36) progress towards the injection site until "further displacement of cartridge housing is blocked by travel limit sleeve **24**." As to element **42**, applicant submits that if the travel limit sleeve is unable to retract into cartridge housing **26**, then the travel limit sleeve **24** is even less able to retract into the cartridge **42**, which is entirely contained by cartridge housing **26**.

Applicant further submits that a skilled person would not have been motivated to modify the outer travel limit sleeve **24** of Haber to be retractable during injection into any of the portions of Haber identified by the Office as a "housing," because such a modification would render this element unsuitable for its intended purpose. If outer travel limit sleeve **24** retracted into these elements during injection, then it would no longer function as a stopper that limits further extension of the needle (e.g., into the skin of a subject) during injection. Therefore, a skilled person would not have been motivated to modify the travel limit sleeve disclosed in Haber to make it retractable during an injection.

Applicant also respectfully disagrees with the Office that the proximal end of the cartridge housing **26** shows a flange, as recited by claim 7. Applicant understands a flange to be a protruding rim, edge, rib, or collar. Figures 3, 4 and 5 in Haber do not appear to depict a flange on housing cartridge **26**, and the specification in Haber does not refer to a flange on element **26** either.

Hutson, which is cited for allegedly disclosing a retractable sleeve and a cap, does not make up for the deficiencies noted above in Haber (or the '463 patent).³ Thus, even if a skilled artisan were to combine the cap disclosed in Hutson with the device in Haber, the combined disclosures would fail to teach or suggest a device with all of the currently recited claim elements. Absent such a teaching or suggestion, the office has failed to establish a *prima facie* case of obviousness.

³ The Office Action mentions '463 patent several times in this rejection. This appears to be an oversight, as the '463 patent does not appear to meet any of the statutory requirements for prior art under 35 U.S.C. § 102. It is a patent by the current inventor; and the patent was not published or issued before the priority date of the current application. Applicant refers the Examiner to the specification (e.g., Figures 1-4) of the earliest priority document for support for the current claims in the present application.

For the reasons presented above, applicant respectfully requests that this rejection be withdrawn as to claim 6 and its dependent claims.

Claim 25 remains rejected as allegedly unpatentable over Haber in view of Hutson. The rejection also mentions U.S. Patent Nos. 5,695,463 (Cherif-Cheikh) and 5,399,170 (Whitley). Applicant respectfully traverses this rejection.

As explained above, Haber and Hutson, either alone or in combination, do not disclose or suggest an injection device with a septum plunger configured (i) to isolate an injectable composition from the needle prior to injection and (ii) to be pierced upon depressing a plunger into the housing, thereby exposing the needle to a composition. As also explained above, the two references, either alone or in combination, fail to disclose a sleeve that covers the needle of the device prior to injection and is slidably connected to the housing such that it retracts into any structure identified by the Office as a housing during the injection.

Applicant again notes that the '463 patent is not available as prior art in a § 103 rejection. More importantly, though, the '463 patent does not describe or suggest (i) a septum plunger configured to separate an injectable composition from the needle prior to injection or (ii) a sleeve that covers the needle of the device prior to the injection and retracts into the housing during the injection. Since the cited references do not teach or suggest all of the limitations the current claims, they are insufficient to establish a *prima facie* case of obviousness.

Whitley, cited for disclosing a locking mechanism, does not make up for the differences noted above in the other references. Furthermore, Whitley does not teach a releasable lock that prevents movement of the plunger into the housing. The locking mechanism disclosed in Whitley allows the plunger to continue moving into the housing as clearly depicted in Figures 11 and 12. Thus, Whitney does not teach or suggest a locking mechanism that includes the limitations of the locking mechanism of pending claim 25.

For the reasons presented herein, applicant respectfully request that the current rejection be withdrawn.

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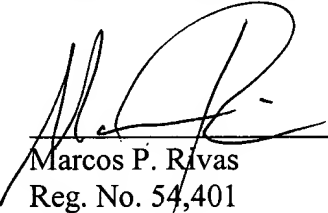
Attorney's Docket No.: 05339-014003 / 023B

CONCLUSION

Applicant requests that all pending claims be allowed. Enclosed is a check for \$1,020, along with a Petition for an Extension of Three Months. Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No. 05339-014003.

Respectfully submitted,

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